

RESPONSE

The numbering of the following response paragraphs mirrors the numbering found in the Detailed Action.

(1) The Examiner indicated the title is not sufficiently descriptive of the invention to which claims are directed. Applicant has amended the specification to replace the originally filed title with a more descriptive title. Applicant respectfully submits the newly amended title fulfills the requirement that the title be brief, technically accurate and descriptive of the invention to which the claims are directed.

(2) The Examiner has rejected claims numbered 1, 2, 7, 16, 18, 23, 24, 26-28, 30-33, 36, 43, 44, and 50-54 under 35 U.S.C. § 112, first paragraph, scope of enablement because: (a) the specification, while being enabling for the preparation and use of compounds of formula (Ia) with Ar as phenyl, does not reasonably provide enablement for the preparation and use of compounds of formula (Ia) with Ar as another ring or ring system; (b) there is no description on how the starting material HQ-Ar-R can be obtained; (c) one skilled in the art would have to carry out undue experimentation to make compounds of formula (Ia) with Ar as another ring or ring system; (d) it appears no compound was tested for activity; and (e) one skilled in the art would have to research extensively to find out which compounds have the ability to modulate PPAR and treat diabetes.

(a) Applicant, acting as its own lexicographer, has specifically defined Ar to be “arylene”, “heteroarylene” or a “divalent heterocyclic group” optionally substituted with one or more C₁₋₆ alkyl or aryl (see page 5 of the specification as filed, lines 20-21). Applicant further defines the term “arylene” at page 20, lines 14-16; “heteroarylene” is defined at page 21, lines 27-33; and “divalent heterocyclic group” is defined at page 25, lines 13-23. Applicant respectfully submits one skilled in the art would be able to prepare and use the compounds of formula (Ia) having Ar as defined in the specification, coupled with the synthesis scheme outlined beginning on page 28 line 1, through page 31, line 10.

The law does not require a specification to be a blueprint in order to satisfy the requirement for enablement under 35 U.S.C. §112, first paragraph. Staehelin v. Secher 24 USPQ 2d 1513, 1516 (B.P.I.A. 1992). The specification need only be reasonable with respect to the art involved; they need not inform the layman nor disclose what the skilled already possess. They need not describe the conventional. . . . The intricacies need not be detailed ad absurdum. General Electric Co. v. Brenner 159 USPQ 335, 337 (D.C. Cir. 1968).

(b) The procedure for obtaining the starting material was known to one skilled in the art as of the date of the present invention, as evidenced by PCT publication WO94/01420, published January 20, 1994. It has been consistently held that the first paragraph of 35 U.S.C. §112 requires nothing more than objective enablement. In satisfying the enablement requirement, an application need not teach, and preferably omits, that which is well known in the art. . . . The law does not require a specification to be a blueprint in order to satisfy the requirement for enablement under 35 U.S.C. §112, first paragraph, Staehelin v. Secher 24 USPQ 2d 1513, 1516 (B.P.I.A. 1992). The Examiner's attention is respectfully directed toward page 62, lines 1-15 of the aforementioned PCT publication. Procedure 1 disclosed therein outlines the synthesis of ethyl 3-(4-hydroxyphenyl)-2-methoxypropanoate, an HQ-Ar-R starting material. The HQ-Ar-R starting material is also disclosed in U.S. Patent No. 5,869,945, at column 45, lines 7-36, issued February 9, 1999.

(c) As discussed in (a) above, the scope of applicants claim does not encompass all rings and ring systems, as suggested by the Examiner. Ar is defined in the specification as "arylene", "heteroarylene" or a "divalent heterocyclic group" optionally substituted with one or more C₁₋₆ alkyl or aryl, (see page 5 of the specification as filed, lines 20-21). Applicant further defines the term "arylene" at page 20, lines 14-16; "heteroarylene" is defined at page 21, lines 27-33; and "divalent heterocyclic group" is defined at page 25, lines 13-23. The specification is not required to be a production specification. Applicant respectfully submits one skilled in the art would be able to prepare and use the compounds of formula (Ia) having Ar as defined in the specification, coupled with the synthesis scheme outlined beginning on page 28 line 1, through page 31, line 10.

The specification need only explain how to make and use the invention without an inordinate amount of experimentation. The fact that experimentation may be complex does not necessarily make it undue if a person skilled in the art typically engages in such experimentation, *In re Borkowski*, 164 USPQ 642, 645 (C.C.P.A. 1970). The test of enablement is not whether experimentation is necessary, but if experimentation *is* necessary, whether it is undue, *In re Angstadt*, 190 USPQ 214, 219 (C.C.P.A. 1976). Applicant submits one skilled in the relevant art is able understand the invention and to use it as a stepping stone to further develop the technology.

(d)/(e) Applicant respectfully directs the Examiner's attention to page 31, line 11 through page 33, line 4 of the specification as filed. The section entitled "Methods" (beginning at page 32, line 14) discusses in detail the testing of the compounds of the invention for activity. Compliance with the enablement requirement of 35 U.S.C. §112, first paragraph, does not require or mandate that a specific example be disclosed, *In re Borkowski*, 1264 USPQ at 645. Applicant respectfully submits that one skilled in the art could easily test compounds of the present invention for activity. Many assays are known to those skilled in the art of molecular biology, biochemistry, genetics, pharmacology and *in vivo* physiology that can be used to screen and discover compounds having the activity described in the present invention, including but not limited to *in vitro* binding assays, cell-based transactivation assays and adipocyte differentiation assays. Many of these assays are easily adapted to an automated high-throughput screening format having the ability to screen thousands of compounds simultaneously. Applicant submits methods for screening compounds for activity is commonplace to one skilled in the art, and because one is expected to screen many compounds in a routine fashion does not make this activity rise to the level of "extensive research". The fact that experimentation may be complex does not necessarily make it undue if a person skilled in the art typically engages in such experimentation, *In re Borkowski*, 164 USPQ 642, 645 (C.C.P.A. 1970).

Applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. §112, first paragraph.

(3) The Examiner has objected to claims 29 and 34 as being dependent upon a rejected base claim, and indicates these claims would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Applicant respectfully asserts that the argument presented above in response to the rejections cited in paragraph (2) of the Detailed Action has obviated the objection. Applicant respectfully requests reconsideration and withdrawal of the objection.

Applicant submits that for the foregoing reasons the rejection under 35 U.S.C. 112, first paragraph has been overcome and the case is now in condition for allowance.

Attached hereto is a marked-up version of the change made to the specification by the current amendment. The attached pages are captioned "Version with Markings to Show Changes Made".

The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application. Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,



Rosemarie R. Wilk-Orescan
Registration Number 45, 220

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Novo Nordisk Pharmaceuticals, Inc.
100 College Road West
Princeton, NJ 08540
(609) 987-5969



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Version with Markings to Show Changes Made

In the specification:

The title of the invention, found on page 1, line 1 of the specification has been amended as follows:

[New Compounds, their Preparation and Use] **Tricyclic Compounds as Nuclear**
Receptor Modulators